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Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-10 EUR-12 EA-12 ISO-00 OES-07 ABF-01
FSE-00 /049 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EA/ANP:TWAJDA(INFO)
EUR/NE:WNEWLIN(INFO)
EUR/NE:SWORREL(INFO)
EUR/WE:JDOBBINS(INFO)
EUR/CE:SKLINGAMAN(INFO)
EA/J:EFEATHERSTONE(INFO)
AF/S:JTAYLOR(INFO)
EUR/WE:AHUGHES (INFO)
EUR/CE:JHURLEY,JR (INFO)
----------126044 012323Z /70
P 012128Z MAY 78
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY BERN PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, BE, UK, FR, GW, JA, SF,

SUBJECT: DEFECTIVE MONOTORING MODULES IN HEMODIALYSIS
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DEVICE (MODULAR PROPORTIONING MACHINE) RECALL T-088-8

1. FDA ADVISES OF THE FOLLOWING DEVICE RECALL:
PRODUCT INVOLVED - TRAVENOL MPM MODULAR PROPORTIONING MACHINE; CATALOG NO. 5M1352-115 VOLT SYSTEM USED DOMESTIC-ALLY AND CATALOG NO. 5M1353-230 VOLT SYSTEM USED INTERNA-TIONALLY. THE MACHINE IS A SINGLE PASS DIALYSIS FLUID

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DELIVERY SYSTEM FOR USE DURING HEMODIALYSIS.

2. PRODUCT IDENTIFICATION - CATALOG NO. 5M1352 MAIN FRAME SERIAL NUMBERS: 045650-1/40; B361A0-1/33; P305A0-1/40; 026330-1/40; B156A0-49; P178AO-3, 59 AND 73; 1225A0-25

3. CATALOG NO. 5M1353 MAIN FRAME SERIAL NUMBERS: 026750-1/40; 045640-1/25; Q439A0-1/27; P305A0-14; 82046-1; 29185-1/5

4. MANUFACTURER: AMERICAN INSTRUMENT COMPANY (AMINCO), DIVISION OF TRAVENOL LABORATORIES, INC., 92299 WASHINGTON BLV., SAVAGE, MARYLAND

5. RECALLING FIRM: ARTIFICIAL ORGANS DIVISION, TRAVENOL LABORATORIES, INC., ONE BAXTER PARKWAY, DEERFIELD ILLINOIS 60015

6. REASON FOR RECALL: SOME OF THE ARTERIAL PRESSURE MODULES AND THE DIALYSATE PRESSURE MODULES OF 5M1352 AND 5M1353 MODULE PROPORTIONING MACHINES MAY NOT PERFORM AS EXPECTED ACROSS THE ENTIRE RANGE OF OPERATION. THIS OCCURS WHEN AN IMPROPER PRESSURE TRANSDUCER HAS BEEN INSTALLED IN THESE MODULES. IN CASES WHERE THIS HAS HAPPENED, OPERATING THE MACHINE WITH DIALYSATE PRESSURE SET BETWEEN -280 MM HG AND -500 MM HG CAN RESULT IN THE UNCLASSIFIED

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CONTROL SYSTEM NOT WORKING PROPERLY. ALSO, IF THE ARTERIAL PRESSURE IS SET ABOVE 135 MM HG, THE ARTERIAL PRESSURE ALARM SYSTEM MAY NOT WORK PROPERLY. ALARM FAILURE COULD RESULT IN A GREATER DEGREE OF ULTRAFILTRATION AND HIGHER FLUID REMOVAL THAN DESIRED. IN ADDITION TO ABOVE, SOME LOTS HAVE A PROBLEM WITH THE CONTROL/LOGIC MODULE, SPECIFICALLY WITH CAPICITORS C2 AND C8. DURING THE MANUFACTURING OF THE PRINTED CIRCUIT BOARD, A CLEANING SOLVENT WAS USED TO REMOVE EXCESS SOLDER. THIS SOLVENT HAS A DETRIMENTAL EFFECT ON CAPACITOR C2 AND C8. OVER A PERIOD OF TIME AND TEMPERATURE, ELECTRICAL LEAKAGE CAN OCCUR WITH THE CAPACITORS. IF THIS HAPPENS, THE ALARM TIMING SEQUENCE WITHIN THE CONTROL/LOGIC MODULES (5M1248) IS EFFECTED SUCH THAT IF AN ALARM CONDITION OCCURS, THE MODULES WILL FLASH THE VISUAL ALARM, BUT THE AUDIBLE ALARM MAY NOT SOUND AND THE UNIT MAY NOT GO INTO BYPASS MODE. THE CONDUCTIVITY OF THE DIALYZING SOLUTION IS MONITORED BY A CONDUCTIVITY MODULE WHICH IS CONNECTED TO THE CONTROL/LOGIC MODULE.

7. FAILURE OF THE CAPICITOR COULD RESULT IN EXTENDED DIALYSIS AND POSSIBLE HEMOLYSIS OF PATIENT'S BLOOD.

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ALARMS ARE SUPPOSED TO ACTIVATE AT POSITIVE OF NEGATIVE
3 PERCENT DEVIATION IN CONDUCTIVITY.

8. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED NOTIFICATION LETTERS DATED FEBRUARY 10, 1978 REQUESTING DISCONTINUANCE OF USE UNTIL MACHINES ARE CHECKED AND PROPER OPERATION CONFIRMED. DEFECTIVE MACHINES WILL HAVE REPLACEMENT LOGIC NODULES CONTAINING A NEW STYLE CAPACITOR. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE REFERRED TO FIRM.

9. CONSIGNEES AS FOLLOWS:

TRAVENOL LABORATORIES PTY. LTD. TRAVENOL AG
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P.O. BOX 88 (OAKES ROAD) UNDERBERG-HAUS
TOONGABBIE N.S.W. 2146, AUSTRALIA INDUSTRIESTRASSE
31
TRAVENOL INTERNATIONAL SERVICES, INC. 8305 DIETLIKON
CHAUSEE DE LA HULPE 130 SWITZERLAND
1050 BRUSSELS, BELGIUM

S.A. TRAVENOL LABORATORIES N.V.
BOULEVARD D. HOURAING
7860 LESSINES, BELGIUM

TRAVENOL LABORATORIES LTD.
CAXTON WAY
THETFORD
NORFOLK, ENGLAND

LABORATORIES TRAVENOL
B.P. 26
78370 PLAISIR, FRANCE

TRAVENOL INTERNATIONAL G.M.B.H.
LADWEHSTER 64A
POSTFACH 20-24-29
D-8000 MUNICH 2, GERMANY

TRAVENOL INTERNATIONAL SERVICES, INC. (TOKYO BRANCH)
ROOMS 1119/1120
KIOI-CHO TBR BUILDING
5-7 KOJI-MACHI
CHYODA-KU, TOKYO 102, JAPAN

KEATINGS PHARMACEUTICALS LTD.
SAMUEL EVANS ROAD
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ACCOUNT OF: KEAGRAMS LTD.
P.O. BOX 256
JOHANNESBURG, SOUTH AFRICA

LABORATORIOS HESPERIA S.A.
POLIGONO INDUSTRIAL VARA DE CUART
APARTADO DE CORREOS 765
CALLE DEL'S GREMIS, 7
VALENCIA 14, SPAIN CHRISTOPHER

NNN

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 01 may 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE110715
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780186-0061
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t197805105/aaaadlpz.tel
Line Count: 184
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 23a2a494-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 22 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2528388
Secure: OPEN
Status: NATIVE
Subject: DEFECTIVE MONOTORING MODULES IN HEMODIALYSIS UNCLASSIFIED UNCLASSIFIED
TAGS: OGEN, ETRD, EIND, TBIO, AS, BE, UK, FR, GE, JA, SF
To: CANBERRA BRUSSELS MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/23a2a494-c288-dd11-92da-001cc4696bcc
Review Markings:
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